

**Medicare Part D Plan Reporting Requirements:
Technical Specifications Document
Contract Year 2012**

Effective Date: January 1, 2012

Prepared by:
Centers for Medicare & Medicaid Services
Center for Medicare
Medicare Drug Benefit and C&D Data Group

Last updated: January 2012

Table of Contents

| | |
|--|----|
| Introduction..... | 3 |
| I. Enrollment and Disenrollment..... | 8 |
| II. Retail, Home Infusion, and Long Term Care Pharmacy Access | 13 |
| III. Access to Extended Day Supplies at Retail Pharmacies | 20 |
| IV. Medication Therapy Management (MTM) Programs..... | 22 |
| V. Prompt Payment by Part D Sponsors | 29 |
| VI. Pharmacy Support of Electronic Prescribing..... | 31 |
| VII. Grievances..... | 33 |
| VIII. Pharmacy & Therapeutics (P&T) Committees / Provision of Part D Functions | 36 |
| IX. Coverage Determinations and Exceptions..... | 39 |
| X. Redeterminations..... | 43 |
| XI. Long-term Care (LTC) Utilization | 45 |
| XII. Fraud, Waste and Abuse Compliance Programs | 51 |
| XIII. Employer/Union-Sponsored Group Health Plan Sponsors | 55 |
| XIV. Plan Oversight of Agents | 58 |
| XV. Summary of CY2012 Part D Reporting Requirements..... | 61 |

Introduction

The Part D Plan Reporting Requirements document provides a description of the reporting sections, reporting timeframes and deadlines, and specific data elements for each reporting section. The document has completed OMB review and approval in compliance with the Paper Reduction Act of 1995, and its OMB control number is #0938-0992. The document is located in HPMS under “In the News”, and posted on the CMS website.

For CY2012, numerous revisions were made to the Part D Plan Reporting Requirements.

Data Elements were revised or removed for the following sections:

- Enrollment and Disenrollment (formerly Enrollment),
- Retail, Home Infusion, and Long-Term Care Pharmacy Access (section I now includes retail pharmacy data file),
- Medicare Therapy Management (MTM) Programs (now includes only the MTM beneficiary-level data file),
- Grievances,
- Coverage Determinations and Exceptions, and
- Redeterminations (formerly Appeals)

Reporting frequency and/or submission deadlines were revised for the following sections:

- Enrollment and Disenrollment (formerly Enrollment),
- Grievances,
- Coverage Determinations and Exceptions,
- Redeterminations (formerly Appeals),
- Long-Term Care (LTC) Utilization, and
- Pharmacy & Therapeutics (P&T) Committees/Provision of Part D Functions

The following sections were removed because the data were being collected elsewhere:

- Pharmaceutical Manufacturer Rebates, Discounts, and Other Price Concessions, and
- Licensure and Solvency, Business Transactions and Financial Requirements; collected via the Fiscal Soundness Report Requirements.

The final CY2012 Reporting Requirements incorporates all of these changes. These technical specifications supplement the Part D Plan Reporting Requirements, and do not change, alter, or add to the data collection described above. They serve to further define data elements and alert Sponsors to how CMS will review and analyze these data.

The purposes of these technical specifications are to help assure a common understanding of the data to be reported by Sponsors, to assist Sponsors in preparing and submitting datasets, to ensure a high level of accuracy in the data reported to CMS, and to reduce the need for Sponsors to correct and resubmit data.

Each Part D reporting section is listed in this document with information regarding the following subjects.

- A. Data element definitions - details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.
- B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
- D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
- E. Notes - additional clarifications to a reporting section. This section incorporates previously answered frequently asked questions.

General Information

Level of Data to be Reported

The level of reporting for each section is specified in the reporting requirements document and within each section in HPMS. Sponsor-level reporting indicates data may be submitted from an organization that is associated with more than one CMS-issued Part D contract. Contract-level reporting indicates data should be entered at the H#, S#, R#, or E# level. Plan-level reporting indicates data should be entered at the PBP level, (e.g. Plan 001 for contract H#, R#, S#, or E). Plan-level reporting is necessary to conduct appropriate oversight and monitoring of some areas.

A summary of the reporting level required for each section is below.

| REPORTING REQUIREMENT SECTION | LEVEL OF REPORTING |
|--|--|
| Enrollment and Disenrollment | Contract |
| Retail, Home Infusion, and Long Term Care Pharmacy Access | Contract (Section I) Plan (Sections II and III) |
| Access to Extended Day Supplies at Retail Pharmacies | Contract |
| Medication Therapy Management (MTM) Programs | Contract |
| Prompt Payment by Part D Sponsors | Contract |
| Pharmacy Support by Electronic Prescribing | Contract |
| Grievances | Plan |
| Pharmacy & Therapeutics (P&T) Committees and Provision of Part D Functions | Contract |
| Coverage Determinations and Exceptions | Plan |
| Redeterminations | Plan |
| Long-Term Care (LTC) Utilization | Contract |
| Fraud, Waste and Abuse Compliance Programs | Contract |
| Employer/Union-Sponsored Group Health Plan Sponsors | Plan |
| Plan Oversight of Agents | Contract |

Timely submission of data

Compliance with these reporting requirements is a contractual obligation of all Part D Sponsors. Compliance requires that the data not only be submitted in a timely manner, but that they also are accurate. Data submissions are due by 11:59 p.m. Pacific time on the date of the reporting deadline.

Only data that reflect a good faith effort by a Sponsor to provide accurate responses to Part D reporting requirements will count as data submitted in a timely manner. Sponsors must not submit “placeholder” data (e.g., submitting the value “0” in reporting fields in HPMS). Sponsors can expect CMS to rely more on compliance notices and enforcement actions in response to reporting requirement failures. Therefore, CMS may issue warning notices or requests for corrective action plans to non-compliant Sponsors. Should the non-compliance persist, CMS may impose intermediate sanctions (e.g., suspension of marketing and enrollment activities) or civil monetary penalties pursuant to Subpart O of 42 C.F.R. Part 423 or contract termination pursuant to Subpart K of 42 C.F.R. Part 423.

If previously submitted data are incorrect, Part D Sponsors should request the opportunity to correct and resubmit data. Part D Sponsors are, responsible for correcting previously submitted data if it is determined the data were erroneous. If CMS changes the technical specifications during the contract year, which requires a change in reporting methodology, CMS is requiring that reports be regenerated for the prior reporting periods for Part D reporting. In order to accommodate data validation activities, data corrections may only be submitted until March 31st following the last quarter or end of year reporting deadline.

Once a reporting deadline has passed, CMS requires the Part D Sponsor to submit a formal request to resubmit any data. HPMS designates this request as a Request Resubmission. Requests for resubmissions will only be approved for 7 days from the date the request is reviewed and approved by CMS. Sponsors should not submit requests to resubmit data until they have data available to submit. Data submitted after the given reporting period deadline shall be considered late, and may not be incorporated within CMS data analyses and reporting. HPMS will not allow the resubmission of data that are identical to the original data submission.

CMS tracks resubmissions, including the number of resubmissions after the deadline. Failure to resubmit after requesting a resubmission is considered as overdue. CMS expects that data are accurate on the date they are submitted. Data resubmissions may only be submitted until March 31st following the last quarter or end of year reporting deadline. CMS urges Plans to store revised data for CMS auditors and data validation reviewers.

The following steps must be followed by a Part D Sponsor to request resubmission:

1. On the HPMS Part D Plan Reporting Start Page, click the Resubmission Request link.
2. Select/complete the following:
 - a. Reporting section (e.g. Appeals);
 - b. Time period (e.g., 1st quarter 2012);
 - c. Select contracts or plans, depending on reporting level; and
 - d. The reason for the resubmission request.
3. CMS will review the information provided and either accept or reject the request for resubmission.

General Data Entry Rules

HPMS will not allow the entry of greater than sign (>); less than sign (<); or semi-colon (;) in any data entry field or uploaded file.

Unless otherwise noted,

- the entry of a zero is allowed,
- the entry of a negative is not allowed, and
- decimals are not allowed.

Exclusions from Reporting

The Part D reporting requirements apply to Part D Sponsors offering the Part D benefit, including PDPs and MA-PDs. They do not apply to MA only Plans. Data relating to Part B

claims should be excluded from these Part D reports, unless otherwise specified. (For example, Coverage Determinations and Exceptions reporting includes Part B related data elements). MA Organizations and Medicare Cost Plans that offer Part D benefits will be required to comply with all reporting requirements contained herein, with the exception of the Employer/Union-Sponsored Group Health Plan Sponsors reporting section, and the Plan Oversight of Agents reporting section. PACE Organizations are excluded from these Part D reporting requirements. Contracts that terminate during the reporting period are also excluded from these reporting requirements.

Based on the information in the Reporting Requirements document and these Technical Specifications, Plans/Sponsors should report data based on interpretation of these documents and be able to support their reporting decisions.

General questions about Part D reporting requirements should be sent via email to: partd-planreporting@cms.hhs.gov.

I. Enrollment and Disenrollment

A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

1. Enrollment

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|--|--|---|
| A. | Total number of enrollment requests received. | The total number of enrollment requests received in the specified time period. | <ul style="list-style-type: none">Field type: Number.Note – this element is based on receipt date, not effective date. |
| B. | Total number of enrollment requests complete at the time of initial receipt (i.e. required no additional information from applicant or his/her authorized representative). | Of the total reported in A, the number of enrollment requests complete at the time of initial receipt (i.e. required no additional information from applicant or his/her representative). | <ul style="list-style-type: none">Field type: Number.Should be a subset of A. |
| C. | Total number of enrollment requests that required requests for additional information. | Of the total reported in A, the number of enrollment requests that required requests for additional information. | <ul style="list-style-type: none">Field type: Number.Should be a subset of A. |
| D. | Total number of enrollment requests denied due to the Sponsor's determination of the applicant's ineligibility to elect the plan (e.g. individual not having a valid enrollment period.) | Of the total reported in A, the number of enrollment requests denied due to the Sponsor's determination of the applicant's ineligibility to elect the plan (e.g. individual not having a valid enrollment period.) | <ul style="list-style-type: none">Field type: Number.Should be a subset of A. |

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|--|--|---|
| E. | Number of incomplete enrollment requests received that are completed within established timeframes. | Of the total reported in C, the number of incomplete enrollment requests received that are completed within established timeframes. | <ul style="list-style-type: none"> Field type: Number. Should be a subset of C. |
| F. | Number of enrollment requests denied due to the applicant or his/her authorized representative not providing information to complete the enrollment request within established timeframes. | Of the total reported in C, the number of enrollment requests denied due to the applicant or his/her authorized representative not providing information to complete the enrollment request within established timeframes. | <ul style="list-style-type: none"> Field type: Number. Should be a subset of C. |
| G. | Number of paper enrollment requests received. | Of the total reported in A, the number of paper enrollment requests received. | <ul style="list-style-type: none"> Field type: Number. Should be a subset of A. |
| H. | Number of telephonic enrollment requests received (if offered). | Of the total reported in A, Number of telephonic enrollment requests received (if offered). | <ul style="list-style-type: none"> Field type: Number. Should be a subset of A. |
| I. | Number of internet enrollment requests received via plan website (if offered). | Of the total reported in A, the number of internet enrollment requests received via plan website (if offered). | <ul style="list-style-type: none"> Field type: Number. Should be a subset of A. |
| J. | Number of Online Enrollment Center (OEC) | Of the total reported in A, the number of Online Enrollment Center (OEC) enrollment requests received. | <ul style="list-style-type: none"> Field type: Number. Should be a subset of A. |

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|---|---|---|
| | enrollment requests received. | | |
| K. | Number of enrollment requests effectuated by sales persons (as defined in Chapter 3 of the Medicare Managed Care Manual). | Of the total reported in A, the number of enrollment requests effectuated by sales persons (as defined in Chapter 3 of the Medicare Managed Care Manual). | <ul style="list-style-type: none"> Field type: Number. Should be a subset of A. For stand-alone PDPs only. |
| L. | Number of enrollment transactions submitted using the SEP Election Period code "S" related to creditable coverage. | Of the total reported in A, the number of enrollment transactions submitted using the SEP Election Period code "S" related to creditable coverage. | <ul style="list-style-type: none"> Field type: Number. Should be a subset of A. |
| M. | Number of enrollment transactions submitted using the SEP Election Period code "S" related to SPAP. | Of the total reported in A, Number of enrollment transactions submitted using the SEP Election Period code "S" related to SPAP. | <ul style="list-style-type: none"> Field type: Number. Should be a subset of A. |
| N. | Number of enrollment transactions submitted using the SEP Election Period code "S" that coordinates with the Medicare Advantage Disenrollment Period. | Of the total reported in A, the number of enrollment transactions submitted using the SEP Election Period code "S" that coordinates with the Medicare Advantage Disenrollment Period. | <ul style="list-style-type: none"> Field type: Number. Should be a subset of A. For stand-alone PDPs only. |
| O. | Number of enrollment | Of the total reported in A, the number of enrollment | <ul style="list-style-type: none"> Field type: Number. Should be a subset |

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|--|--|------------------|
| | transactions submitted using the SEP Election Period code "S" for individuals affected by a contract nonrenewal, plan termination or service area reduction. | transactions submitted using the SEP Election Period code "S" for individuals affected by a contract nonrenewal, plan termination or service area reduction. | of A. |

2. Disenrollment

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|--|---|--|
| A. | Total number of voluntary disenrollment requests received in the specified time period. | The total number of voluntary disenrollment requests received in the specified time period. | <ul style="list-style-type: none"> Field type: Number. Note – this element is based on receipt date, not effective date. |
| B. | Total number of disenrollment requests complete at the time of initial receipt (i.e. required no additional information from enrollee or his/her authorized representative). | Of the total reported in A, the number of disenrollment requests complete at the time of initial receipt (i.e. required no additional information from enrollee or his/her representative). | <ul style="list-style-type: none"> Field type: Number. Should be a subset of A. |
| C. | Total number of disenrollment requests denied by the Sponsor for any reason. | Of the total reported in A, the number of disenrollment requests denied by the Sponsor for any reason. | <ul style="list-style-type: none"> Field type: Number. Should be a subset of A. |

- B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
- CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and does not indicate that submitted data are incorrect, or that resubmissions are required.
 - The percent of enrollment requests denied by the contract will be examined for outlier data. After accounting for the number of enrollment requests filed, contracts with values above the 98th percentile for their contract type will be flagged as outliers.
 - CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.
- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
- N/A.
- D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
- To be determined.
- E. Notes – additional clarifications to a reporting section.
- EGWPs and all-800 series plans are waived from this reporting section. For contracts with both non-800 series and 800-series plans, data for the 800-series plan(s) may be excluded.
 - Data are based on enrollment requests or submitted transactions. Auto-assignments should not be included in these data.
 - Reporting should include all enrollment requests received during the period, including those which may subsequently “fail” after the period, and/or reporting deadline.

II. Retail, Home Infusion, and Long Term Care Pharmacy Access

A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

I. Retail Pharmacy Access, Home Infusion (HI), and Long Term Care (LTC) Pharmacy Access: Three data files to be uploaded through the HPMS at the CMS Part D Contract level.

- Required File Format is ASCII File - Tab Delimited.
- The file name extension should be “.TXT”
- File name=Pharmacies_ (RT, HI or LTC)_(CONTRACTNAME)_(CONTRACTYEAR).txt
- Replacing ‘(RT, HI or LTC) with the corresponding type of pharmacies
- Pharmacies_(RT)_(CONTRACTNAME)_(CONTRACTYEAR).txt
- Pharmacies_ (HI)_(CONTRACTNAME)_(CONTRACTYEAR).txt
- Pharmacies_ (LTC)_(CONTRACTNAME)_(CONTRACTYEAR).txt
- And also replacing (CONTRACTNAME)’ with the Part D Contract’s name, and CONTRACTYEAR) with the year.
- Plans are required to submit data for their entire service area, even if there are no HI and/or LTC pharmacies in specific territories/states.

Retail Record Layout

| Field Name | Field Type | Maximum Field Length | Field Description | Sample Field Value(s) |
|-------------------------|----------------------------|----------------------|---|--------------------------|
| NPI_Number | CHAR Always Required | Exactly 10 | Indicate the contracted Retail pharmacy NPI number (exactly 10 digits). | 1234567809 |
| Pharmacy_Name | CHAR Always Required | 150 | Provide the name of the Retail pharmacy. | CVS Pharmacy |
| Pharmacy_Street_Address | CHAR Always Required | 150 | Enter the street address of the pharmacy. | 1212 North Luther Street |
| Pharmacy_City_Address | CHAR Always Required | 75 | Enter the city in which the pharmacy is located. | Wichita |
| Pharmacy_State_Address | CHAR Always Required | 2 | Enter the state abbreviation in which the pharmacy is located. | MO |

| Field Name | Field Type | Maximum Field Length | Field Description | Sample Field Value(s) |
|--------------------------|-------------------------|-------------------------|---|------------------------------------|
| Pharmacy_Zip_Address | CHAR Always Required | Exactly 5 or Exactly 10 | Enter the pharmacy's zip code. | 22203 or 22203-1234 |
| Pharmacy_Network_Type_PN | CHAR Always Required | 1 | Is the pharmacy network preferred? | P = Preferred N = Non-Preferred |
| Chain_YN | CHAR Always Required | 1 | Is the pharmacy a chain? | N = No Y = Yes |
| Independent_YN | CHAR Always Required | 1 | Is the pharmacy independent? | N = No Y = Yes |
| Group_Purchasing_YN | CHAR Always Required | 1 | Does the pharmacy allow group purchasing? | N = No Y = Yes |

Home Infusion Record Layout

| Field Name | Field Type | Maximum Field Length | Field Description | Sample Field Value(s) |
|-------------------------|-------------------------|-------------------------|--|--------------------------|
| NPI_or_NCPDP Number | CHAR Always Required | Exactly 10 or exactly 7 | Indicate the contracted Home Infusion pharmacy NPI number (exactly 10 digits), or indicate the NCPDP number (exactly 7 digits) if the NPI number is not available. | 1234567809 or 1024510 |
| Pharmacy_Name | CHAR Always Required | 150 | Provide the name of the Home Infusion pharmacy. | CVS Pharmacy |
| Pharmacy_Street_Address | CHAR Always Required | 150 | Enter the street address of the pharmacy. | 1212 North Luther Street |

| Field Name | Field Type | Maximum Field Length | Field Description | Sample Field Value(s) |
|--------------------------|-------------------------|-------------------------|---|------------------------------------|
| Pharmacy_City_Address | CHAR Always Required | 75 | Enter the city in which the pharmacy is located. | Wichita |
| Pharmacy_State_Address | CHAR Always Required | 2 | Enter the state abbreviation in which the pharmacy is located. | MO |
| Pharmacy_Zip_Address | CHAR Always Required | Exactly 5 or Exactly 10 | Enter the pharmacy's zip code. | 22203 or 22203-1234 |
| States_Licensed | CHAR Always Required | No Limit | <p>Enter the states in which the pharmacy is licensed. Use the state abbreviation.</p> <p>This field should be comma-delimited; state abbreviations should be separated with a comma.</p> <p>Please note: the contract must have at least one pharmacy licensed in each state that is covered in the contract's service area.</p> | MA, VA, KS |
| Pharmacy_Network_Type_PN | CHAR Always Required | 1 | Is the pharmacy network preferred? | P = Preferred N = Non-Preferred |
| Chain_YN | CHAR Always Required | 1 | Is the pharmacy a chain? | N = No Y = Yes |
| Independent_YN | CHAR Always Required | 1 | Is the pharmacy independent? | N = No Y = Yes |

| Field Name | Field Type | Maximum Field Length | Field Description | Sample Field Value(s) |
|---------------------|-------------------------|----------------------|---|-----------------------|
| Group_Purchasing_YN | CHAR Always Required | 1 | Does the pharmacy allow group purchasing? | N = No Y = Yes |

LTC Pharmacy Record Layout

| Field Name | Field Type | Maximum Field Length | Field Description | Sample Field Value(s) |
|-------------------------|-------------------------|-------------------------|--|--------------------------|
| NPI_or_NCPDP_Number | CHAR Always Required | Exactly 10 or Exactly 7 | Indicate the contracted LTC pharmacy NPI number (exactly 10 digits), or indicate the NCPDP number (exactly 7 digits) if the NPI number is not available. | 1234567809 or 1024510 |
| Pharmacy_Name | CHAR Always Required | 150 | Provide the name of the LTC pharmacy. | CVS Pharmacy |
| Pharmacy_Street_Address | CHAR Always Required | 150 | Enter the street address of the pharmacy. | 1212 North Luther Street |
| Pharmacy_City_Address | CHAR Always Required | 75 | Enter the city in which the pharmacy is located. | Wichita |
| Pharmacy_State_Address | CHAR Always Required | 2 | Enter the state abbreviation in which the pharmacy is located. | MO |
| Pharmacy_Zip_Address | CHAR Always Required | Exactly 5 or Exactly 10 | Enter the pharmacy's zip code. | 22203 or 22203-1234 |

| Field Name | Field Type | Maximum Field Length | Field Description | Sample Field Value(s) |
|--------------------------|-------------------------|----------------------|--|------------------------------------|
| States_Licensed | CHAR Always Required | No Limit | <p>Enter the states in which the pharmacy is licensed. Use the state abbreviation.</p> <p>This field should be comma-delimited; state abbreviations should be separated with a comma.</p> <p>Please note: the contract must have at least one pharmacy in each state that is covered in the contract's service area.</p> | MA, VA, KS |
| Pharmacy_Network_Type_PN | CHAR Always Required | 1 | Is the pharmacy network preferred? | P = Preferred N = Non-Preferred |
| Chain_YN | CHAR Always Required | 1 | Is the pharmacy a chain? | N = No Y = Yes |
| Independent_YN | CHAR Always Required | 1 | Is the pharmacy independent? | N = No Y = Yes |
| Group_Purchasing_YN | CHAR Always Required | 1 | Does the pharmacy allow group purchasing? | N = No Y = Yes |

- II. Sponsors receiving pharmacy access waivers: Data elements to be entered into the HPMS at the Plan (PBP) level for only those MA-PD and Cost Plans that own and operate their own pharmacies and have received a waiver of the any willing pharmacy requirement.

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|---|---|--|
| A | Number of prescriptions provided by all pharmacies owned and operated | Number of prescriptions provided in the time period by all pharmacies owned and operated. | <ul style="list-style-type: none"> Should be mutually exclusive. Field type: Number. |
| B | Number of prescriptions provided at all pharmacies contracted | Number of prescriptions provided in the time period at all pharmacies contracted. | <ul style="list-style-type: none"> Should be mutually exclusive. Field type: Number. |

- III. Sponsors receiving pharmacy access waivers: Data elements to be entered into the HPMS at the Plan (PBP) level for only those MA-PD and cost plans that own and operate their own retail pharmacies and have received a waiver of the retail pharmacy convenient access standards. These plans are not exempt from reporting Retail Pharmacy Access listed above.

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|--|--|--|
| A | Number of prescriptions provided by retail pharmacies owned and operated | Number of prescriptions provided in the time period by retail pharmacies owned and operated. | <ul style="list-style-type: none"> Should be mutually exclusive. Field type: Number. |
| B | Number of prescriptions provided at all retail pharmacies contracted | Number of prescriptions provided in the time period at all retail pharmacies contracted. | <ul style="list-style-type: none"> Should be mutually exclusive. Field type: Number. |

- B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
- CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and does not indicate that submitted data are incorrect, or that resubmissions are required.

- The number of contracted retail pharmacies reported for this section will be combined with data from the Pharmacy Support of Electronic Prescribing section to determine outliers for the percent of retail pharmacies enabled to receive electronic prescribing.
 - CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.
- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
- For section I, the States Licensed field must include ALL states in the plan's service area for the HI and LTC data file uploads. Note, a contract with both employer-only (800 series) market portions of its service area and individual market plans serving the total or part of its service area, will be required to report data only for the states in the individual plans' active service area. A contract with an entirely employer-only (800 series) or an entirely individual market service area will be required to report data for all states in its active service area.
- D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
- CMS will evaluate to ensure access standards are met.
- E. Notes – additional clarifications to a reporting section.
- Employer groups are not exempt from this reporting section.
 - The Retail, HI and LTC pharmacy network templates can be found in the HPMS reporting module, under Documentation -> Download File Templates.
 - The download entitled Beneficiary Count Data is a national file used for PDP and MA-PD sponsors, and is updated annually. The file is posted on the Prescription Drug Contracting section of CMS' website in January. To locate the file on the web, go to http://www.cms.gov/PrescriptionDrugCovContra/04_RxContracting_ApplicationGuidance.asp, and click on the application guidance link on the left side navigation bar.
 - For subsection I. HI and LTC Pharmacy Access, HPMS will allow the entry of either NPI # (10 digits) or NCPDP # (7 digits) into the "NPI_or_NCPDP_Number field". Thus, exactly 10 characters or exactly 7 characters must be entered in this field. For Retail Pharmacy Access, HPMS will allow the the entry of the NPI # only (10 digits) into the "NPI_Number field." Thus exactly 10 characters must be entered in this field.

III. Access to Extended Day Supplies at Retail Pharmacies

- A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

Data elements to be entered into the HPMS at the CMS Contract level:

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|--|---|---|
| A | Number of contracted retail pharmacies that are contracted to dispense an extended day supply of covered Part D drugs. | The number of contracted retail pharmacies in a Contract's service area that are contracted to dispense an extended day supply of covered Part D drugs as of the last day of the reporting period. PDPs and regional PPOs will report by State for PDPs and regional PPOs, and by service area for local MA-PD plans. | <ul style="list-style-type: none">• Should not be greater than the contract's total number of contracted retail pharmacies.• Field type: Number. |

- B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
- CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and does not indicate that submitted data are incorrect, or that resubmissions are required.
 - Data should be a whole number.
 - CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.
- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
- Should not be greater than the contract's total number of contracted retail pharmacies.
- D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
- CMS will evaluate access to extended day supplies at contracted retail pharmacies by:
 - (1) calculating a ratio of the total number of contracted retail pharmacies that are contracted to dispense an extended day supply of covered Part D drugs to the total number of contracted retail pharmacies in a plan's service area, and
 - (2) conducting an outlier test relative to all other contracts.

E. Notes – additional clarifications to a reporting section.

- This reporting requirement applies only to those Part D contracts that include in their networks mail-order pharmacies offering extended day supplies of covered Part D drugs. CMS considers an extended day supply to be any days supply provided which is greater than the number of days identified by a Part D contract as constituting a one-month supply. We note that a one-month supply cannot exceed 34 days.
- If a contract has in its network any mail-order pharmacies that offer extended day supplies, it must offer extended day supplies at some retail pharmacies in its network and must report how many of its network retail pharmacies offer this benefit.
- Contracts that do not have network mail-order pharmacies that offer extended day supplies are exempt from reporting; therefore HPMS will not display this section to exempt contracts.
- The term “contracted retail pharmacies” means the number of contracted retail pharmacies within a contract’s service area. If the contract has a national service area, the contract would report a total number of pharmacies in their national network. However, if the contract does not have a national service area, the contract should not report a total number of pharmacies in their national network.
- Direct Contracts and 800 series employer group plans within MAPD and PDP contracts are excluded from this report regardless if extended day supplies are offered.

IV. Medication Therapy Management (MTM) Programs

- A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.
- A data file containing the following fields for targeted beneficiaries enrolled in the contract's Medication Therapy Management (MTM) program at any time in the reporting period will be uploaded using Gentran or Connect Direct:
 - You must not include additional information outside of what is dictated in the record layout.
 - You must not include a header row.
 - Submissions that do not strictly adhere to the record layout will be rejected.

Important notes and clarifications are provided below in E. Notes..

| Beneficiaries Eligible for MTM Record Layout | | | | | |
|--|---------------|--------------|----------------|--------------|--|
| Field Name | Field Type | Field Length | Start Position | End Position | Field Description |
| Contract Number | CHAR REQUIRED | 5 | 1 | 5 | The Contract Number (e.g., H1234, S1234) for your organization. |
| HICN or RRB Number | CHAR REQUIRED | 12 | 6 | 17 | <p>For each distinct beneficiary identified to be eligible for MTM (who met your MTM program's targeting criteria based on CMS requirements and was automatically enrolled in the MTM program) at any time in the reporting period, provide the unique number that the Social Security Administration assigns to each Medicare beneficiary, which is the Health Insurance Claim number (HICN). For Railroad Retirement Board (RRB) beneficiaries, provide the RRB number in this field instead of the HICN.</p> <p>Distinct beneficiaries should only be reported once per file. If the beneficiary's HICN changed during the reporting period, only report the most current HICN.</p> |

| Beneficiaries Eligible for MTM Record Layout | | | | | |
|--|-----------------------------|--------------|----------------|--------------|---|
| Field Name | Field Type | Field Length | Start Position | End Position | Field Description |
| Beneficiary First Name | CHAR REQUIRED | 30 | 18 | 47 | The first name of each beneficiary identified to be eligible for MTM in the reporting period. |
| Beneficiary Middle Initial | CHAR OPTIONAL | 1 | 48 | 48 | The middle initial of each beneficiary identified to be eligible for MTM in the reporting period. |
| Beneficiary Last Name | CHAR REQUIRED | 30 | 49 | 78 | The last name of each beneficiary identified to be eligible for MTM in the reporting period. |
| Beneficiary Date of Birth | DATE REQUIRED | 8 | 79 | 86 | The date of birth for each beneficiary identified to be eligible for MTM in the reporting period (CCYYMMDD, e.g., 19400101). |
| LTC Enrollment | CHAR REQUIRED | 1 | 87 | 87 | <p>For each beneficiary eligible for MTM, indicate if the beneficiary was a long-term care (LTC) resident <u>for the entire time</u> they were enrolled in MTM during the reporting period. This should be Y (yes), N (no), or U (unknown).</p> <p>If the beneficiary opted-out of MTM enrollment, indicate whether they were an LTC resident with Y (yes), N (no), or U (unknown).</p> |
| Date of MTM program Enrollment | DATE REQUIRED | 8 | 88 | 95 | For each beneficiary identified to be eligible for the MTM in the reporting period, enter the date they were automatically enrolled (CCYYMMDD, e.g., 20120101). |
| Date MTM program Opt-out, if applicable | DATE Conditionally REQUIRED | 8 | 96 | 103 | This should be a date field (CCYYMMDD, e.g., 20120101). <i>The date must be provided if the beneficiary opted out of MTM.</i> |

| Beneficiaries Eligible for MTM Record Layout | | | | | |
|--|-----------------------------------|--------------|----------------|--------------|---|
| Field Name | Field Type | Field Length | Start Position | End Position | Field Description |
| Reason Participant Opted-out of MTM program (Death; Disenrollment from Plan; Request by beneficiary; or Other). Required if Date of MTM Opt-out is applicable. | CHAR Conditionally REQUIRED | 2 | 104 | 105 | For each beneficiary with a disposition status of opted out of MTM program, the reason must be provided. Reasons for opting out must be one of the following: 01 - Death; 02 - Disenrollment from Plan; 03 - Request by beneficiary; or 04 - Other. Note: If Date MTM Opt-out is provided, then Reason participant Opted-out of MTM is required. |
| Offered annual comprehensive medication review | CHAR REQUIRED | 1 | 106 | 106 | For each beneficiary enrolled in MTM program, indicate if the beneficiary was offered an interactive, person-to-person comprehensive medication review. This should be Y (yes) or N (no). |
| If offered a comprehensive medication review, date of (initial) offer | DATE Conditionally REQUIRED | 8 | 107 | 114 | This should be a date field (CCYYMMDD, e.g. 20120601). The date must be provided if the beneficiary was offered an interactive, person-to-person comprehensive medication review. |
| Received annual comprehensive medication review | CHAR REQUIRED | 1 | 115 | 115 | For each beneficiary enrolled in MTM program, indicate if the beneficiary received an interactive, person-to-person comprehensive medication review. This should be Y (yes) or N (no). |
| If received a comprehensive medication review, first date of annual comprehensive medication review. | DATE Conditionally REQUIRED | 8 | 116 | 123 | This should be a date field (CCYYMMDD, e.g. 20120601). The date must be provided if the beneficiary received an interactive, person-to-person comprehensive medication review. If more than 1 CMR is received, up to 3 dates will be allowed. |

| Beneficiaries Eligible for MTM Record Layout | | | | | |
|---|-----------------------------------|--------------|----------------|--------------|---|
| Field Name | Field Type | Field Length | Start Position | End Position | Field Description |
| If received a comprehensive medication review, second date of annual comprehensive medication review. | DATE Conditionally REQUIRED | 8 | 124 | 131 | This should be a date field (CCYYMMDD, e.g. 20120601). The date must be provided if the beneficiary received an interactive, person-to-person comprehensive medication review. If more than 1 CMR is received, up to 3 dates will be allowed. |
| If received a comprehensive medication review, third date of annual comprehensive medication review. | DATE Conditionally REQUIRED | 8 | 132 | 139 | This should be a date field (CCYYMMDD, e.g. 20120601). The date must be provided if the beneficiary received an interactive, person-to-person comprehensive medication review. If more than 1 CMR is received, up to 3 dates will be allowed. |
| Number of targeted medication reviews | NUMERIC REQUIRED | 2 | 140 | 141 | For each beneficiary enrolled in MTM, indicate the number of targeted medication reviews conducted. This should be a numeric field. If the beneficiary had no targeted medication reviews, enter 0. |
| Number of prescriber interventions | NUMERIC REQUIRED | 2 | 142 | 143 | For each beneficiary enrolled in MTM, indicate the number of prescriber interventions made. This should be a numeric field. If the beneficiary had no prescriber interventions, enter 0. |

| Beneficiaries Eligible for MTM Record Layout | | | | | |
|---|------------------|--------------|----------------|--------------|--|
| Field Name | Field Type | Field Length | Start Position | End Position | Field Description |
| Number of changes to drug therapy made as a result of MTM interventions | NUMERIC REQUIRED | 2 | 144 | 145 | For each beneficiary enrolled in MTM, indicate the number of changes to drug therapy as a result of MTM interventions. Changes include, <u>but are not limited to</u> , dosage changes, therapeutic or generic substitutions, and discontinuation or addition of therapy. This should be a numeric field. If the beneficiary had no drug therapy changes made as a result of MTM interventions, enter 0. |

- B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
- CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and does not indicate that submitted data are incorrect, or that resubmissions are required.
 - The percent of eligible MTM program enrollees who opted out of an MTM program will be examined for outlier data.
 - The percent of MTM program enrollees who received a CMR will be examined for outlier data. LTC beneficiaries will be excluded and dates of enrollment and opt-out will be considered.
 - CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.
- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
- If "Date Participant Opted-out of MTM" is provided, then "Reason participant Opted-out of MTM" is required.
- D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
- CMS will also evaluate the percent of beneficiaries that opt-out of MTM.
 - CMS will evaluate the percent of beneficiaries who are offered and receive a comprehensive medication review.
 - CMS will evaluate initial MTM outcomes, as reported as prescriber interventions and changes to drug therapy.

E. Notes - additional clarifications to a reporting section.

- Only beneficiaries identified to be eligible for MTM (who met the contract's MTM program's targeting criteria based on CMS requirements and was automatically enrolled in the MTM program) at any time in the reporting period should be reported. Members who receive MTM services outside of the CMS-required MTM criteria defined by the plan should be excluded from this reporting.
- The period of MTM eligibility and enrollment is a contract year; therefore eligibility, enrollment, etc. are counted and reported distinctly for each contract year. A beneficiary may be reported for multiple program years if they remain eligible for MTM.
 - At the start of each contract year, beneficiaries who continue to meet the eligibility criteria should be automatically enrolled in MTM and should be reported.
 - Also, beneficiaries who are newly targeted for eligibility in the MTM program for the new contract year should be reported.
 - Beneficiaries who no longer meet the eligibility criteria at the start of the new MTM program year would not be automatically enrolled and would no longer be reported.
- A targeted beneficiary should only be reported once per contract year per contract file. If the beneficiary's HICN changed during the reporting period, only report the most current HICN.
- Sponsors have discretion in the designation of a data source in order to complete the "LTC Enrollment" field of the MTM beneficiary level data file. Sponsors must be able to present rationale for this designation.
- Sponsors should refer to Chapter 5, Section 10.2 of the Prescription Drug Benefit Manual for a description of the types of facilities which should be considered LTC.
- Sponsors should refer to Chapter 7 of the Prescription Drug Benefit Manual for more information about required MTM services and the definition for a CMR which includes an interactive, person-to-person consultation performed by a pharmacist or qualified provider with written summaries.
- For reporting CMR offers, the beneficiary must receive the offer. Therefore, returned mail or incorrect phone numbers do not count as an offer.
- For targeted beneficiaries enrolled in the MTM program that are in a LTC setting, sponsors are not required to offer the CMR, but still must perform quarterly medication reviews and offer interventions targeted to the beneficiaries' prescribers.
- CMS requires that sponsors perform targeted medication reviews (TMRs) for all targeted beneficiaries enrolled in the MTM program, no less often than quarterly. Part D sponsors must assess the findings of these reviews to determine if a follow-up intervention is necessary and if the intervention is warranted for the beneficiary and/or prescriber.
- The enrolled beneficiaries may refuse or decline individual services without having to opt-out (disenroll) from the program. For example, if an enrolled beneficiary declines the annual CMR or another follow-up intervention, the sponsor should still offer interventions to the prescriber and perform targeted

medication reviews at least quarterly to assess medication use on an on-going basis.

- The number of prescriber interventions should be reported based on the count of unique interventions made to prescribers; it is not equal to the total number of prescribers that received intervention recommendations.
- Sponsors should report the number of interventions to the prescriber and not each individual problem identified in these communications. For example, if 3 drug therapy problems were identified for a member and were sent to the prescriber in a fax, this should be reported as 1 intervention.
- If a beneficiary is deceased prior to their MTM eligibility date, the plan should not report the beneficiary.
- Changes to drug therapy as a result of MTM interventions include, and are not limited to, the examples listed above (dosage changes, therapeutic or generic substitutions, and discontinuation or addition of therapy). **Sponsors should not limit data reported to the examples provided.** Sponsors should retain documentation supporting the number of changes to drug therapy reported to CMS.
- Sponsors should not upload the MTM beneficiary-level data file if they have no MTM enrollees to report. Instead Sponsors should report that they have no MTM enrollees via e-mail to: partd-planreporting@cms.hhs.gov.

V. Prompt Payment by Part D Sponsors

A. Data element definitions - details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|--|---|---|
| A. | Total number of paid claims. | The total number of paid claims. | <ul style="list-style-type: none">Field type: Number. |
| B. | Total number of paid electronic claims. | The total number of paid electronic claims. | <ul style="list-style-type: none">Field type: Number.Should be a subset of A. |
| C. | Total number of paid non-electronic claims. | The total number of paid non-electronic (e.g. paper) claims. | <ul style="list-style-type: none">Field type: Number.Should be a subset of A. |
| D. | Total number of paid electronic claims which were not paid timely. | The total number of paid electronic claims which were not paid timely, according to appropriate time-periods. | <ul style="list-style-type: none">Field type: Number.Should be a subset of B. |
| E. | Number of paid non-electronic claims which were not paid timely | The total number of paid non-electronic claims which were not paid timely, according to appropriate time-periods. | <ul style="list-style-type: none">Field type: Number.Should be a subset of C. |
| F. | Interest amount paid on electronic claims that were not paid timely. | The interest dollar amount paid on electronic claims that were not paid timely. | <ul style="list-style-type: none">Field type: Number.Should be rounded up to the nearest dollar. |
| G. | Interest amount paid on non-electronic claims that were not paid timely. | The interest dollar amount paid on non-electronic claims that were not paid timely. | <ul style="list-style-type: none">Field type: Number.Should be rounded up to the nearest dollar. |

- B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
- CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and does not indicate that submitted data are incorrect, or that resubmissions are required.
 - The percent of paid claims that were electronic will be examined for outlier data. After accounting for the total number of paid claims, contracts with values below 95% will be flagged as outliers.
 - The percent of total claims, electronic claims and non-electronic claims paid late will be examined for outlier data. Contracts with values above 5% on any of these measures will be flagged as outliers.
 - The interest per late electronic and non-electronic claim will be examined for outlier data. Contracts with values above \$5 on either measure will be flagged as outliers.
 - CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.
- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
- The total number of paid claims (Element A) should equal the sum of paid electronic and non-electronic claims (Element B+C).
- D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
- To be determined.
- E. Notes - additional clarifications to a reporting section. This section incorporates previously answered frequently asked questions.
- Interest paid on claims that were not paid timely should be rounded up to the nearest dollar. For example, \$0.01 would be reported as \$1.00.
 - A clean claim that is paid within the required 14 days (when the claim was submitted electronically) or 30 days (when the claim was submitted non-electronically) is counted as being paid promptly, regardless of whether it is subsequently reversed.
 - A clean claim that is not paid within the required 14 days (when the claim was submitted electronically) or 30 days (when the claim was submitted non-electronically) is late regardless of any future reversals of that claim.
 - A clean claim that is not paid prior to the reversal and the reversal occurred prior to the 14th day (when the claim was submitted electronically) or the 30th day (when the claim was submitted non-electronically) should not be counted as a clean claim.

VI. Pharmacy Support of Electronic Prescribing

A. Data element definitions - details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|---|---|--|
| A. | Number of retail pharmacies in a Contract's service area enabled to receive electronic prescriptions in compliance with Part D standards. | The number of retail pharmacies in a Contract's service area (by State for PDPs and regional PPOs, and by service area for local MA-PD plans) enabled to receive electronic prescriptions in compliance with Part D standards as of the last day of the reporting period specified. | <ul style="list-style-type: none"> Field type: Number. |
| B. | Number of long-term care pharmacies in a Contract's service area enabled to receive electronic prescriptions in compliance with Part D standards. | The number of long-term care pharmacies in a Contract's service area (by State for PDPs and regional PPOs, and by service area for local MA-PD plans) enabled to receive electronic prescriptions in compliance with Part D standards as of the last day of the reporting period specified. | <ul style="list-style-type: none"> Field type: Number. Include Long-Term Care pharmacies holding a license for state(s) in the sponsor's service area. |
| C. | Number of home infusion pharmacies in a Contract's service area enabled to receive electronic prescriptions in compliance with Part D standards. | The number of home infusion pharmacies in a Contract's service area (by State for PDPs and regional PPOs, and by service area for local MA-PD plans) enabled to receive electronic prescriptions in compliance with Part D standards as of the last day of the reporting period specified. | <ul style="list-style-type: none"> Field type: Number. Include Home Infusion pharmacies holding a license for state(s) in the sponsor's service area. |

- B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
- CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and does not indicate that submitted data are incorrect, or that resubmissions are required.
 - The percent of retail pharmacies enabled to receive electronic prescribing will be examined for outlier data. All contracts with values below 15% will be flagged as outliers.
 - CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.
 -
- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
- Ensure data reported for this section are consistent with data reported in the Retail, Home Infusion, and Long-Term Pharmacy Access reporting section.
 - No more than 100% of retail, HI, or LTC pharmacies should be enabled to receive electronic prescribing. Contracts with 800 series plans are exempt from this check as the number of pharmacies associated with 800 series plans is not reported in the Pharmacy Access section.
- D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
- These data will be analyzed with other Sponsor-reported data, including lists of contracted retail, LTC, and HI network pharmacies from the Retail, Home Infusion, and Long-Term Pharmacy Access reporting section, in order to determine the percentage of pharmacies enabled to receive electronic prescriptions.
- E. Notes - additional clarifications to a reporting section. This section incorporates previously answered frequently asked questions.
- N/A

VII. Grievances

A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

Data elements to be entered into the HPMS at the CMS Plan (PBP) level:

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|---|---|---|
| A | Enrollment, plan benefits, or pharmacy access – Total number of grievances | The number of grievances related to Enrollment, plan benefits, or pharmacy access. | <ul style="list-style-type: none"> Field type: Number. Should be based on the date the decision was made. |
| B | Enrollment, plan benefits, or pharmacy access – Number of grievances in which timely notification was given | The number of grievances related to Enrollment, plan benefits, or pharmacy access that resulted in timely notification of decision. | <ul style="list-style-type: none"> Field type: Number. Should be a subset of A. |
| C | Customer service – Total number of grievances | The number of grievances related to Customer service. | <ul style="list-style-type: none"> Field type: Number. Should be based on the date the decision was made. |
| D | Customer service – Number of grievances in which timely notification was given | The number of grievances related to Customer service that resulted in timely notification of decision. | <ul style="list-style-type: none"> Field type: Number. Should be a subset of C. |
| E | Coverage determinations and Redeterminations process (e.g. untimely decisions) – Total number of grievances | The number of grievances related to Coverage determinations and Redeterminations process. | <ul style="list-style-type: none"> Field type: Number. Should be based on the date the decision was made. |
| F | Coverage determinations | The number of grievances related to Coverage | <ul style="list-style-type: none"> Field type: Number. Should be a subset |

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|--|---|---|
| | and Redeterminations process (e.g. untimely decisions) – Number of grievances in which timely notification was given | determination and Redetermination process that resulted in timely notification of decision. | of E. |
| G | Other – Total number of grievances | The number of grievances related to a category not listed above. | <ul style="list-style-type: none"> Field type: Number. Should be based on the date the decision was made. |
| H | Other – Number of grievances in which timely notification was given | The number of grievances related to a category not listed above that resulted in timely notification of decision. | <ul style="list-style-type: none"> Field type: Number. Should be a subset of G. |

- B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
- CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and does not indicate that submitted data are incorrect, or that resubmissions are required.
 - The percent of beneficiaries filing grievances will be examined for outlier data. After accounting for enrollment, plans with values above the 95th percentile for their plan type or below the 5th percentile for their plan type will be flagged as outliers.
 - The percent of grievances for which the plan provided timely notification of its decision will be examined for outlier data. All plans with values below the 5th percentile for their plan type will be flagged as outliers.
 - CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.
- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
- Confirm those data elements listed above as subsets of other elements.
- D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.

- The total grievance rate per 1,000 enrollees is equal to the sum of the total number of grievances divided by average enrollments, multiplied by 1,000.

$$\text{Total Grievance Rate per 1,000 enrollees} = \frac{\text{Total \# Grievances}}{\text{Avg. Enrollment}} \times 1,000$$

- The grievance rate by category per 1,000 enrollees is equal to the sum of the grievance element divided by average enrollment, multiplied by 1,000.

$$\text{Grievance Rate by Category per 1,000 enrollees} = \frac{\text{Grievance Element}}{\text{Avg. Enrollment}} \times 1,000$$

- CMS will order plans based on rates of grievances per 1,000 enrollees and determine the percentile ranking.
- CMS will also correlate grievances with complaints in the CMS complaints tracking module (CTM).

E. Notes – additional clarifications to a reporting section.

- All grievances filed with a PBP should be counted in a category. Grievances may be filed by enrollees, non-enrollees or appointed representatives.
- Grievances should be categorized by the type of grievance as determined by the PBP, and reported based on the grievance decision date.
- An enrollee's request for a coverage determination or a redetermination for drug coverage is not considered a grievance. Refer to Subpart M section 423.564 of the Voluntary Medicare Prescription Drug Benefit for more information about Part D grievances, including required timeframes for Sponsors to notify enrollees about their decisions.
- Complaints received by 1-800 Medicare or recorded in the CTM should be excluded from these data.
- In the event that a beneficiary files multiple grievances during a reporting period, plans should consider the following:
 - If a beneficiary files a grievance and then files a grievance again on the same issue, prior to the Plan's decision or the deadline for decision notification (whichever is earlier), then that should only be counted as one grievance.
 - If a beneficiary files a grievance and then files a subsequent grievance on the same issue after the Plan's decision or deadline for decision notification (whichever is earlier), then that counts as a separate grievance.
 - If a beneficiary files a grievance about two different issues, then they are counted as separate grievances.
- MA-PDs should report a grievance as either a Part C or Part D grievance, depending on the process the plan used to investigate/resolve the grievance. For most complaints or grievances, a plan will be able to determine which is more applicable. For the minority of cases where a clear distinction is not available for a MA-PD, cases should be reported as Part C grievances.

VIII. Pharmacy & Therapeutics (P&T) Committees / Provision of Part D Functions

A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

Section I. Pharmacy & Therapeutics (P&T) Committees

Data elements to be entered into the HPMS at the CMS Contract level:

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|---------------------------|--|--|
| A | Changes to P & T | Have there been any changes to the P&T Committee membership within the reporting period? If “No” – no more data entry is required. | <ul style="list-style-type: none">• Yes.• No. |
| | Confidentiality agreement | Does this contract operate under a confidentiality agreement? See notes for specific directions regarding how this information should be reported to CMS. | <ul style="list-style-type: none">• Yes.• No. |
| | Changes reported to CMS | If “Yes” to confidentiality agreement question - Have these changes been provided to CMS per those agreements? | <ul style="list-style-type: none">• Yes.• No. |
| | | If “No” to confidentiality agreement question - Have these changes been reflected within the Contract Management Module? | <ul style="list-style-type: none">• Yes.• No. |

Section II: Provision of Part D Functions

Data elements to be entered into the HPMS at the CMS Contract level:

| Element Letter | Element Name | Definition | • Allowable Values |
|----------------|-----------------------------|--|--|
| A | Changes to the organization | Have changes been made to the Provision of Part D functions? If “No” – no more data entry is required. | <ul style="list-style-type: none">• Yes.• No. |
| | Changes reported to CMS | If “Yes” to changes to the organization question, - Have these changes been reflected within the Contract Management Module? | <ul style="list-style-type: none">• Yes.• No. |

- B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
- CMS’ outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and does not indicate that submitted data are incorrect, or that resubmissions are required.
 - CMS will identify contracts which report no changes occurred in either their P&T Committee membership or the entities that provide Part D functions, yet, changes were reflected in the HPMS Contract management Module.
 - CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.
- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
- N/A
- D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
- CMS will identify contracts that indicated changes to either P&T Committee membership or the entities providing Part D functions and have not yet been reported to CMS.
- E. Notes – additional clarifications to a reporting section.
- Part D Sponsors operating under a confidentiality agreement with a third party representative with respect to their P&T Committee must follow the following steps to submit P&T Committee membership changes.
 - Complete the “Pharmacy and Therapeutics Committee Disclosure Form” and “Certification for P&T” MS Word documents. These forms can be found in the HPMS Plan Reporting Module. When completing the Disclosure form, additional rows may be added to Tables B and C; no other format changes

may be made to these documents. Both documents must be submitted to CMS for notification of P&T Committee changes.

- The completed “Pharmacy and Therapeutics Committee Disclosure Form” should be renamed as, “P&T Committee_(Contract Number)_ (Date)”. The date should be in the following format: mo_day_year. An example filename is P&T Committee_H1234_03112012.doc.
- A Part D Sponsor, at the contract level, should input all P&T Committee member names in this section. CMS understands that the entire list of names may represent multiple P&T Committees serving different PBPs within one contract.
- The completed “Certification for P&T” document should be renamed as, “P&T Certification_(Contract Number)_(Date)” The date should be in the following format: mo_day_year.
- An example filename is P&T Certification_H1234_03_11_2012.doc.
- The Certification document should contain an electronic signature.
- The naming convention used for P&T Committee Confidentiality documents that apply to more than one contract number should be file name and date. It should be indicated in the email to partd-planreporting@cms.hhs.gov that the submission is for multiple contracts,
- Submit both documents via email to partd-planreporting@cms.hhs.gov. Documents may be sent by either the third party organization or directly from the Part D Sponsor. The subject line must read “P&T Committee Changes – Confidential Submission”. Sponsors may encrypt the email or password protect the documents. If the documents are password protected, Sponsors must provide the password to CMS in a follow-up email and clearly indicate the files to which the passwords applies.
- Provision of Part D function:
 - Sponsors should refer to the HPMS Contract management module for information regarding Part D Sponsor related functions; this module contains the actual information regarding these entities.
- Reporting is required regardless of the plan’s enrollment status.

IX. Coverage Determinations and Exceptions

A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

Data elements to be entered into the HPMS at the CMS Plan (PBP) level:

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|---|---|--|
| A | Number of Pharmacy Transactions | The total number of pharmacy transactions during the reporting period. | <ul style="list-style-type: none">Field type: Number.Part D Sponsors should report the total number of pharmacy transactions for Part D drugs by fill date (not batch date), including approved, rejected, and those with final disposition of reversed. CMS understands these numbers may include multiple transactions for the same prescription drug claim. |
| B | Number of Pharmacy Transactions rejected due to formulary restrictions, including non-formulary status, PA requirements, step therapy, and quantity limits (QL) | Of the total reported in A, the number of pharmacy transactions rejected due to formulary restrictions. These include rejections due to non-formulary status, prior authorization requirements, step therapy, and quantity limits (QL). | <ul style="list-style-type: none">Field type: Number.Should be a subset of A.Part D Sponsors should report the total number of pharmacy transactions, excluding those rejections due to early refills. CMS understands these numbers may include multiple transactions for the same prescription drug claim.Rejections due to early refills should be excluded. |

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|---|--|--|
| C | Total number of Prior Authorizations (PA) made in the reporting period. | The total number of PAs made in the reporting period. | <ul style="list-style-type: none"> Field type: Number. Should be based on the date the decision was made. Exception requests to PA criteria should not be included in this data element; these are reported in element F. |
| D | Number of timely PA decisions | The number of timely PA decisions in the reporting period. | <ul style="list-style-type: none"> Field type: Number. Should be a subset of C. |
| E | Number of approved PAs (PA requirements satisfied) | The number of approved PAs (PA requirements satisfied) in the reporting period. | <ul style="list-style-type: none"> Field type: Number. Should be a subset of C. |
| F | Number of Utilization Management (UM) exceptions made in the reporting period | The number of UM exceptions made in the reporting period. Includes exceptions to UM tools (e.g. prior authorizations, quantity limits, or step therapy requirements). | <ul style="list-style-type: none"> Field type: Number. Should be based on the date the decision was made. PA requests should not be included in this element; these should be reported in element C. |
| G | Number of timely UM exception decisions | The number of timely UM exception decisions in the reporting period. Includes exceptions to UM tools (e.g. prior authorizations, quantity limits, or step therapy requirements). | <ul style="list-style-type: none"> Field type: Number. Should be a subset of F. |
| H | Number of favorable UM exceptions | The number of favorable UM exceptions in the reporting period. Includes exceptions to UM tools (e.g. prior authorizations, quantity limits, or step therapy requirements). | <ul style="list-style-type: none"> Field type: Number. Should be a subset of F. |
| I | Total number of tier exceptions made in the reporting period. | The number of tier exceptions made in the reporting period. | <ul style="list-style-type: none"> Field type: Number. Should be based on the date the decision was made. |

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|---|---|---|
| J | Number of timely tier exception decisions | The number of timely tier exception decisions in the reporting period. | <ul style="list-style-type: none"> Field type: Number. Should be a subset of I. |
| K | Number of favorable tier exceptions | The number of favorable tier exceptions in the reporting period. | <ul style="list-style-type: none"> Field type: Number. Should be a subset of I. |
| L | Total number of formulary exceptions made in the reporting period | The number of formulary exceptions made in the reporting period. | <ul style="list-style-type: none"> Field type: Number. Should be based on the date the decision was made. |
| M | Number of timely formulary exception decisions | The number of timely formulary exception decisions in the reporting period. | <ul style="list-style-type: none"> Field type: Number. Should be a subset of L. |
| N | Number of favorable formulary exceptions | The number of favorable formulary exceptions in the reporting period. | <ul style="list-style-type: none"> Field type: Number. Should be a subset of L. |

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.

- CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and does not indicate that submitted data are incorrect, or that resubmissions are required.
- The rate of utilization management, tier, and formulary exception requests per 1,000 enrollees will be examined for outlier data. After accounting for enrollment, plans with values above the 95th percentile for their plan type or below the 5th percentile for their plan type will be flagged as outliers.
- The rate of prior authorization exception requests per 1,000 enrollees will be examined for outlier data. After accounting for enrollment, plans with values above the 95th percentile for their plan type or below the 5th percentile for their plan type will be flagged as outliers.
- The percent of utilization management, tier, and formulary exceptions requests approved by the plan will be examined for outlier data. After accounting for the number of non-formulary, tier, and utilization management exceptions requests filed, plans with values above the 95th percentile or below the 5th percentile for their plan type will be flagged as outliers.
- The percent of prior authorization exceptions requests approved by the plan will be examined for outlier data. After accounting for the number of prior authorization exceptions requests filed, plans with values above the 95th percentile or below the 5th percentile for their plan type will be flagged as outliers.

- CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.
- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
- Confirm those data elements listed above as subsets of other elements.
- D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
- CMS will evaluate exception rates per 1000 enrollees and will trend rates from quarter to quarter and from previous years.
- E. Notes – additional clarifications to a reporting section.
- Requests for coverage determinations or exceptions that are withdrawn should be excluded from this reporting.
 - Prior authorization requests/approvals that relate to Part B versus Part D coverage should be included in this reporting. A drug that is ultimately covered under Part B should be considered for this reporting as a denial for Part D coverage.
 - Excluded drug categories should not be included in this reporting.
 - A request for an exception to a plan's PA criteria could be processed as a coverage determination or as a redetermination, depending if the plan has received the beneficiary's initial PA request, and denied it. Plans' reporting should be based on the manner in which each request for exception to a plan's PA criteria is processed.
 - Part D Plans should include all types of quantity limit rejects in these data. (Including but not limited to claim rejections due to quantity limits or time rejections (e.g. a claim is submitted for 20 tablets/10 days, but is only approved for 10 tablets/5 days).
 - Beneficiaries that are "grand-fathered" on drugs and have UM requirements waived are not considered as exception requests; and therefore, should not be reported.
 - Requests for coverage determinations and exceptions should be reported based on the decision date
 - Cases forwarded to the Independent Review Entity (IRE) due to the Plan's failure to make a timely decision should not be included in this reporting.
 - Partial denials should be reported as approvals.

X. Redeterminations

A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

Data elements to be entered into the HPMS at the CMS Plan (PBP) level:

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|--|--|--|
| A | Number of Redeterminations made in the reporting period | The total number of redeterminations made for in the reporting period. | <ul style="list-style-type: none">Field type: Number.Should not include requests that were withdrawn or dismissed.Should be based on date the redetermination decision was made during the reporting time-period, regardless of the date the redetermination request was received or when the member was notified of the decision. |
| B | Number of Redeterminations made within required timeframes | Of the total reported in A, the number of redetermination made within required timeframes. | <ul style="list-style-type: none">Field type: Number.Should be a subset of A. |
| C | Number of partially favorable redeterminations | Of the total reported in A, the number of partially favorable redeterminations. | <ul style="list-style-type: none">Field type: Number.Should be a subset of A. |
| D | Number of fully favorable redeterminations | Of the total reporting in A, the number of fully favorable redeterminations. | <ul style="list-style-type: none">Field type: Number.Should be a subset of A. |

B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.

- CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and does not indicate that submitted data are incorrect, or that resubmissions are required.

- The rate of redeterminations per 1,000 enrollees will be examined for outlier data. After accounting for enrollment, plans with values above the 95th percentile for their plan type or below the 5th percentile for their plan type will be flagged as outliers.
- The percent of redeterminations resulting in a full or partial reversal of the original decision will be examined for outlier data. After accounting for the number of redeterminations filed, plans with values above the 95th percentile or below the 5th percentile for their plan type will be flagged as outliers.
- CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.

C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.

- Plans should validate that data elements B and C are less than or equal to data element A.
- All data elements should be positive values.

D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.

- Rates of appeals will be calculated per 1,000 enrollees. This means the total appeal rate per 1,000 enrollees is equal to the sum of the total number of appeals divided by average enrollment, times 1,000.

$$\text{Total Appeal Rate per 1,000 enrollees} = \frac{\text{Total \# Appeals}}{\text{Avg. Enrollment}} \times 1,000$$

E. Notes – additional clarifications to a reporting section.

- This reporting includes only redeterminations, the first level of appeal.
- Excluded drug categories should not be included in this reporting.
- Redetermination requests should be reported based on the decision date.
- In the event that a beneficiary files one redetermination request containing multiple distinct disputes (i.e., multiple drugs), plans should count each dispute as a separate request.

XI. Long-term Care (LTC) Utilization

- A. Data element definitions – details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

Data elements A, B, C and E will be entered into HPMS.

Data listed under data element D will be uploaded into HPMS, per the file layout listed below at the contract level for each state or service area.

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|-------------------------------------|---|--|
| A. | Number of network LTC pharmacies | <p>The total number of network LTC pharmacies in the service area.</p> <p>PDPs and regional PPOs will report at the State level. MA-PDs will report at the Contract level.</p> | <ul style="list-style-type: none"> Field type: Number. Count a pharmacy that is both LTC and retail in both elements A and B, and report corresponding claims/utilization specific to business lines in elements D and E. If claims/utilization cannot be split, report the pharmacy and its claims/utilization as a LTC pharmacy only (data elements A and D). Include LTC pharmacies that do not have utilization; in element D, enter zeroes for number and cost of prescriptions. Include any LTC pharmacy that is active in the network for 1 or more days in the entire reporting period. Include Long-Term Care pharmacies holding a license for the state(s) in the sponsor's service area. |
| B. | Number of network retail pharmacies | <p>The total number of network retail pharmacies in the service area.</p> <p>PDPs and regional PPOs will report for at the State level. MA-PDs will report at the Contract level.</p> | <ul style="list-style-type: none"> Field type: Number. Count a pharmacy that is both LTC and retail in both elements A and B, and report corresponding claims/utilization specific to business lines in elements D and E. If claims/utilization cannot be split, report the pharmacy and its |

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|--|--|---|
| | | | <p>claims/utilization as a LTC pharmacy only (data elements A and D).</p> <ul style="list-style-type: none"> • Include retail pharmacies that do not have utilization. • Include any retail pharmacy that is active in the network for 1 or more days in reporting period. |
| C. | Number of beneficiaries in LTC facilities for whom Part D drugs have been provided | <p>The total number of distinct beneficiaries in LTC facilities for whom Part D drugs have been provided.</p> <p>PDPs and regional PPOs will report at the State level. MA-PDs will report at the Contract level.</p> | <ul style="list-style-type: none"> • Field type: Number. • Do not report beneficiaries that received only claims for non-Part D drugs, e.g. excluded or OTC drugs. • Do not report beneficiaries more than once; the total number should be a distinct count of beneficiaries. • Claims with location code 03 may be used to identify enrollees. The LTI report may be another tool for this reporting. • Claims with location code 04 or 07 should not be included. • Include any LTC pharmacy that is active in the network for 1 or more days in reporting period. |
| D. | <p>For each network LTC pharmacy in the service area:</p> <p>a. LTC pharmacy name</p> <p>b. LTC pharmacy NPI</p> <p>c. Contract entity name of LTC pharmacy</p> <p>d. Chain code</p> | <p>Non-formulary drugs are drugs that are not on a Plan's Part D formulary but approved for coverage via the exceptions process, or under the transition policy.</p> <p>PDPs, regional PPOs, and MA-PDs will report for the entire service area.</p> | <ul style="list-style-type: none"> • These data will be uploaded into HPMS, please refer to file layout below, "Long-term Care (LTC) Pharmacy Data – File Record Layout". • Any LTC pharmacy that is active in the network for 1 or more days in reporting period should be included. • Any Long-Term Care pharmacy holding a license for the state(s) in the sponsor's service area should be included. • Enter "Not Available" in the |

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|--|--|---|
| | <p>of LTC pharmacy</p> <p>e. Number of 31-day equivalent formulary prescriptions dispensed</p> <p>f. Number of 31-day equivalent non-formulary prescriptions dispensed</p> <p>g. Cost of formulary prescriptions</p> <p>h. Cost of non-formulary prescriptions</p> | | <p>Chain Code field, if the pharmacy chain code is unknown or does not exist.</p> <ul style="list-style-type: none"> • A formulary drug is a drug included on a Part D plan's CMS approved formulary, including drugs with utilization management (UM) restrictions e.g. prior authorization or step therapy. • A non-formulary drug is a drug that is not included on a Part D plan's CMS approved formulary. • Part D Sponsors should report the total number of prescriptions dispensed for Part D drugs by fill date (not batch date). • The number of 31-day equivalent prescriptions is calculated by summing the days supply of all covered Part D prescriptions dispensed, and dividing by 31. • Cost of prescriptions is defined as the sum of the total ingredient Cost, dispensing fee, sales tax and vaccine administration fee. The ingredient cost should reflect the Plan's negotiated price. |
| E. | <p>In aggregate, for all retail pharmacies in the service area:</p> <p>a. Number of 30-day equivalent formulary prescriptions dispensed</p> <p>b. Number of</p> | <p>Non-formulary drugs are drugs that are not on a Plan's Part D formulary but approved for coverage via the exceptions process, or under the transition policy.</p> <p>PDPs, regional PPOs, and MA-PDs will</p> | <ul style="list-style-type: none"> • Should be based on network retail pharmacies in the service area. • Number of prescriptions is a numeric field, and cost of prescriptions is a currency field. • A formulary drug is a drug included on a Part D plan's CMS approved formulary, including drugs with utilization |

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|---|-------------------------------|---|
| | 30-day equivalent non-formulary prescriptions dispensed c. Cost of formulary prescriptions d. Cost of non-formulary prescriptions | report at the Contract level. | management (UM) restrictions e.g. prior authorization or step therapy. <ul style="list-style-type: none"> • A non-formulary drug is a drug that is not included on a Part D plan's CMS approved formulary. • Part D Sponsors should report the total number of prescriptions dispensed for Part D drugs by fill date (not batch date). • The number of 30-day equivalent prescriptions is calculated by summing the days supply of all covered Part D prescriptions dispensed, and dividing by 30. • Cost of prescriptions is defined as the sum of the total ingredient Cost, dispensing fee, sales tax and vaccine administration fee. The ingredient cost should reflect the Plan's negotiated price. • Include any retail pharmacy that is active in the network for 1 or more days in reporting period. |

Long-term Care (LTC) Pharmacy Data – File Record Layout
(Data listed in data element D above)

Required File Format = ASCII File - Tab Delimited

Do not include a header record

Filename extension should be “.TXT”

| Field Name | Field Type | Field Length | Field Description | Sample Field Value(s) |
|---------------------------------------|------------------|---------------|--|------------------------------|
| NPI_Number | NUM Required | Exactly 10 | Indicate the contracted LTC pharmacy NPI number (exactly 10 digits), if the NPI number is not available. Enter 9999999999 if a pharmacy's NPI cannot be identified. | 1234567809 |
| Pharmacy_Name | CHAR Required | 150 | Provide the name of the LTC pharmacy in the service area. | ABC LTC Pharmacy |
| Contract_Name | CHAR Required | 150 | Enter the Contract entity name of the LTC pharmacy in the service area. | Health Care Pharmacies, Inc. |
| Chain_Code | CHAR Required | 150 | Enter the chain code of the LTC pharmacy in the service area. | ABC |
| Formulary_Prescriptions_Dispensed | NUM Required | 7 | Enter the number of 31-day equivalent formulary prescriptions for each network LTC pharmacy in the service area. | 9999999 |
| Non_Formulary_Prescriptions_Dispensed | NUM Required | 7 | Enter the number of 31-day equivalent non-formulary prescriptions for each network LTC pharmacy in the service area. | 9999999 |
| Cost_Formulary_Prescriptions | NUM Required | 10 | Enter the cost of formulary prescriptions for each network LTC pharmacy in the service area. 2 decimal points are allowed. | 99999999.99 |

| Field Name | Field Type | Field Length | Field Description | Sample Field Value(s) |
|--|-----------------|--------------|---|-----------------------|
| Cost_ Non_Formulary_ Prescriptions | NUM Required | 10 | Enter the cost of non-formulary prescriptions for each network LTC pharmacy in the service area. 2 decimal points are allowed. | 99999999.99 |

- B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
- CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and does not indicate that submitted data are incorrect, or that resubmissions are required.
 - CMS may apply new quality assurance checks and threshold validations based upon data received from Part D Plans.
- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
- N/A
- D. Analysis- steps taken by CMS to evaluate reported data, as well as how other data sources may be monitored along with these data.
- Rates of formulary and non-formulary utilization and costs will be calculated by LTC pharmacy and entity. Retail rates will be used for comparative purposes.
 - The percent of enrollees receiving prescriptions from LTC facilities will be taken into account when identifying LTC utilization outliers.
- E. Notes – additional clarifications to a reporting section.
- Claims from all facilities considered LTC should be included, e.g. ICFMR.
 - Claims during a transition period should be included.
 - Medicare Secondary Payer (MSP) claims should be excluded.
 - The fill date should be used when reporting this section.
 - The type of pharmacy (LTC or retail) is in accordance with the type of contract between the pharmacy and the Part D sponsor. For example, only those pharmacies with a retail contract should be included in data elements B and E.
 - For Contract_Name, the LTC pharmacy name can be entered if it is not associated with a contract entity, the LTC pharmacy name.
 - To complete the data entry portion of this section, contracts will first need to upload their LTC Pharmacy Data file. Once the file has been successfully uploaded, contracts will then be able to enter data for data elements A, B, C and E.
 - Employer-Direct PDPs, Employer-Direct PFFS, and any other contracts that have only 800 series plans are excluded from this reporting.

XII. Fraud, Waste and Abuse Compliance Programs

A. Data element definitions - details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

| Element Letter | Element Name | Definition | Allowable Values |
|-----------------------|--|---|--|
| A. | Number of potential fraud and abuse incidents related to inappropriate billing (i.e. inadvertent billing errors, duplicate billing). | The number of potential fraud and abuse incidents related to inappropriate billing. Inappropriate billing by pharmacies should be included. | <ul style="list-style-type: none">• Field type: Number.• Subset of F. |
| B. | Number of potential fraud and abuse incidents related to providing false information. | The number of potential fraud and abuse incidents related to providing false information. | <ul style="list-style-type: none">• Field type: Number.• Subset of F. |
| C. | Number of potential fraud and abuse incidents related to doctor shopping/drug seeking beneficiary. | The number of potential fraud and abuse incidents related to doctor shopping/drug seeking beneficiary. | <ul style="list-style-type: none">• Field type: Number.• Subset of F. |
| D. | Number of potential fraud and abuse incidents related to attempting to steal identity/money. | The number of potential fraud and abuse incidents related to attempting to steal identity/money. | <ul style="list-style-type: none">• Field type: Number.• Subset of F. |

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|--|--|---|
| E. | Number of potential fraud and abuse incidents related to other areas not listed above. | The number of potential fraud and abuse incidents related to other areas not listed above (e.g. OIG exclusion list, and broker/ agent complaints). | <ul style="list-style-type: none"> Field type: Number. Subset of F. |
| F. | Total number of potential fraud and abuse incidents identified. | The total number of potential fraud and abuse incidents identified. | <ul style="list-style-type: none"> Field type: Number. |
| G. | Number of potential incidents identified through internal efforts. | Of the total reported in F, the number identified through internal efforts. | <ul style="list-style-type: none"> Field type: Number. This is a subset of F. |
| H. | Number of potential incidents received from external sources. | Of the total reported in F, the number of incidents received from external sources. Incidents reported through the Complaints Tracking Module (CTM) or as grievances should be included. | <ul style="list-style-type: none"> Field type: Number. This is a subset of F. |
| I. | Number of inquiries initiated by the Sponsor. | The number of inquiries initiated by the Sponsor as a result of potential fraud and abuse incidents. | <ul style="list-style-type: none"> Field type: Number. |
| J. | Number of corrective actions initiated by the Sponsor. | The number of corrective actions initiated by the Sponsor as a result of potential fraud and abuse incidents. | <ul style="list-style-type: none"> Field type: Number. |
| K. | Number of potential fraud and abuse incidents referred to CMS for action. | The number of potential fraud and abuse incidents referred to CMS for action; includes referrals to CMS staff, MEDICs, or other CMS designated program safeguard contractor. | <ul style="list-style-type: none"> Field type: Number. Should be a subset of F. |

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|--|---|---|
| L. | Number of potential fraud and abuse incidents referred to federal law enforcement for action. | The number of potential fraud and abuse incidents referred to federal law enforcement for action. This includes referrals to the OIG, FBI, DEA, and FDA. | <ul style="list-style-type: none"> Field type: Number. Should be a subset of F. |
| M. | Number of potential fraud and abuse incidents referred to local law enforcement for action. | The number of potential fraud and abuse incidents referred to local law enforcement for action; this includes but is not limited to referrals to state, county, township, or province police. | <ul style="list-style-type: none"> Field type: Number. Should be a subset of F. |
| N. | Number of potential fraud and abuse incidents referred to State Insurance Commissioners (SICs) or state licensing authorities. | The number of potential fraud and abuse incidents referred to State Insurance Commissioners (SICs) or state licensing authorities. | <ul style="list-style-type: none"> Field type: Number. Should be a subset of F. |

- B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
- CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and does not indicate that submitted data are incorrect, or that resubmissions are required.
 - CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.
- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
- The sum of elements A, B, C, D, and E should be equal to element F.
- D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
- To be determined.
- E. Notes - additional clarifications to a reporting section. This section incorporates previously answered frequently asked questions.

- Employer Direct plan sponsors are exempt from this reporting section.
- Part D Sponsors may voluntarily report aggregate data related to their anti-fraud, waste and abuse activities.

XIII. Employer/Union-Sponsored Group Health Plan Sponsors

- A. Data element definitions - details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

Employer Group Plan Sponsor Upload File Format

Required File Format = ASCII File - Tab Delimited

Do not include a header record.

Filename extension should be ".TXT"

There can be multiple records per plan.

| Field Name | Field Type | Field Length | Field Description | Sample Field Value(s) |
|-------------------------|-------------------|-----------------------------|--|---|
| Contract_Number | CHAR Required | 5 Exactly | Provide the CMS issued contract number being offered to the Employer Group Plan Sponsor. (Note: The system shall validate the contract number is valid.) | H1234 |
| Plan_ID | NUM Required | 3 Exactly | Provide the ID (with leading zeros as appropriate) of the Plan Benefit Package (PBP) being offered to the Employer Group Plan Sponsor. (Note: This is a numeric field only. The system shall validate the plan ID is valid.) | 801 or 001 |
| Employer_Legal_Name | CHAR Required | 150 | Provide the legal name of the Employer Group Plan Sponsor. | United Parcel Service |
| Employer_DBA_Name | CHAR Optional | 150 | If applicable provide the doing business as (DBA) name of the Employer Group Plan Sponsor. | United Parcel Service Employees Association |
| Employer_Federal_Tax_ID | NUM Required | Minimum of 9, Maximum of 20 | Provide the federal tax ID of the Employer Group Plan Sponsor. (Note: This is a numeric field only. This must be a minimum of 9 digits and cannot be more than 20 digits.) | 223849199 |
| Employer_Street_Address | CHAR Required | 150 | Provide the street address of the Employer Group Plan Sponsor headquarters. | 1212 North Luther Street |
| Employer_City_Address | CHAR Required | 75 | Provide the city in which the Employer Group Plan Sponsor headquarters is located. | Wichita |

| Field Name | Field Type | Field Length | Field Description | Sample Field Value(s) |
|----------------------------|------------------|--------------|---|--|
| Employer_State_Address | CHAR Required | 2 | Provide the state abbreviation in which the Employer Group Plan Sponsor headquarters is located. (Note: The system shall validate the state abbreviation is appropriate.) | MO |
| Employer_Zip_Address | NUM Required | 10 | Provide the Employer Group Plan Sponsor headquarters' zip code. (Note: This is a numeric field only.) This field must be a minimum of 5 digits and leading zeroes are required.) | 00123 00123-0123 001230123 |
| Employer_Sponsor_Type | NUM Required | 1 | Indicate the Employer Group Plan Sponsor Type; acceptable values provided as sample. (Note: This is a numeric field only. The system shall validate the value is 1 through 3.) | 1=Employer 2=Union 3=Trustees of a Fund |
| Employer_Organization_Type | NUM Required | 1 | Indicate the Employer Group Plan Organization Type; acceptable values provided as sample. (Note: This is a numeric field only. The system shall validate the value is 1 through 7.) | 1=State Government 2=Local Government 3=Publicly Traded Corp. 4=Privately Held Corp. 5=Non-Profit 6=Church Group 7=Other |
| Employer_Contract_Type | NUM Required | 1 | Indicate the Employer Group Plan Contract Type; acceptable values provided as sample. (Note: This is a numeric field only. The system shall validate the value is 1 through 3.) | 1=Insured 2=ASO 3=Other |
| Employer_Start_Date | NUM Required | 6 | Provide the month and year when the Employer Group Plan Sponsor started or will start with the Plan. The format is MMYYYY, so the sample is intended to depict June 2008 (062008). (Note: This is a numeric field only. The system shall validate that the month is a value of 01 to 12.) | 062008 |
| Employer_Enrollment | NUM Required | 7 | Provide the current enrollment for the Employer Group Plan | 9999999 |

| Field Name | Field Type | Field Length | Field Description | Sample Field Value(s) |
|------------|------------|--------------|---|-----------------------|
| | | | Sponsor. (Note: This is a numeric field only. Do not include commas.) | |

- B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
- CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and does not indicate that submitted data are incorrect, or that resubmissions are required.
 - CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.
- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
- N/A.
- D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
- To be determined.
- E. Notes - additional clarifications to a reporting section. This section incorporates previously answered frequently asked questions.
- This reporting requirement applies only to individual PDPs and "800 series" PDPs offered to employers. MA-PD plans already report these data as part of the Part C reporting requirements and are therefore exempt from this Part D reporting. Individual PDPs and "800 series" PDPs that have been identified as having the same parent organization as a MA-PD plan are also exempt from this Part D reporting.
 - HPMS displays one module for reporting both Part C and Part D Employer/Union-Sponsored Group Health Plan Sponsors data.
 - Each Part D contract will upload a file containing plan level data.
 - Refer to Part C Technical Specifications for additional guidance.

XIV. Plan Oversight of Agents

A. Data element definitions - details for each data element reported to CMS, including examples, methods for calculations, and how various data elements are associated.

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|--|--|--|
| A. | Total number of agents. | Total number of agents. This includes only agents who are licensed to sell on behalf of the sponsor, either by being a direct employee or by contractual arrangement, regardless of whether the agent is actively selling during the reporting period. | <ul style="list-style-type: none">Field type: Number. |
| B. | Number of agents investigated based on complaints. | Number of agents investigated based on complaints. | <ul style="list-style-type: none">Field type: Number.Should be a subset of A. |
| C. | Number of agents receiving disciplinary actions from the Sponsor based on complaints. | Number of agents receiving disciplinary actions from the Sponsor based on complaints. | <ul style="list-style-type: none">Field type: Number.Should be a subset of B. |
| D. | Number of complaints reported to State by contract. | Number of complaints reported to State by contract. This includes only those complaints originating with the contract that are then reported to the State. | <ul style="list-style-type: none">Field type: Number. |
| E. | Number of agents whose selling privileges were revoked by the plan based on conduct or discipline. | Number of agents whose selling privileges were revoked by the plan based on conduct or discipline. | <ul style="list-style-type: none">Field type: Number.Should be a subset of A. |

| Element Letter | Element Name | Definition | Allowable Values |
|----------------|---------------------------------------|---|---|
| F. | Number of agent-assisted enrollments. | Number of agent-assisted enrollments. This is a count of any enrollment effective during the reporting period that a beneficiary used the services of a licensed agent to complete the enrollment process. Examples of this include, but are not limited to: enrollments completed through a call center staffed by licensed agents, in person sales appointments, or public sales meetings where a licensed agent collects the forms. Agent assisted enrollments include both individual and group enrollments in which a licensed agent assisted in completing the enrollment process. The count of agent assisted enrollments should be enrollments that are as a direct result of the participation of the group of agents reported in element A. Plans should not include cancelled enrollments. | <ul style="list-style-type: none"> Field type: Number. |

- B. QA checks/Thresholds - procedures used by CMS to establish benchmarks in order to identify outliers or data that are potentially erroneous.
- CMS' outlier notifications serve only to give Part D sponsors the opportunity to correct submitted data if needed, and does not indicate that submitted data are incorrect, or that resubmissions are required.
 - The rate of complaints per 1,000 enrollees will be examined for outlier data. After accounting for enrollment, contracts with values above one complaint per 1,000 enrollees or below 0.1 complaints per 1,000 enrollees will be flagged as outliers.
 - CMS may apply new or adjust existing quality assurance checks and threshold validations based upon data received from Part D Plans.
- C. Edits and Validation Checks - validation checks that should be performed by each Part D Sponsor prior to data submission.
- The number of agents investigated based on complaints (Element B) should not exceed the total number of agents (Element A).

- The number of agents receiving disciplinary actions based on complaints (Element C) should not exceed the number of agents investigated based on complaints (Element B).
- D. Analysis- how CMS will evaluate reported data, as well as how other data sources may be monitored.
- To be determined.
- E. Notes - additional clarifications to a reporting section. This section incorporates previously answered frequently asked questions.
- This reporting requirements section applies only to stand-alone PDP contracts that do not also have MA-PD contracts. PDP contracts that have been identified as having the same parent organization as a MA-PD contract are exempt from this Part D reporting. MA-PD contracts already report these data as part of the Part C reporting requirements and are therefore also exempt from this Part D reporting.
 - 800 series plans and employer/union group contracts are exempt from this reporting section. For contracts with both non-800 series and 800-series plans, data for the 800-series plan(s) may be excluded.
 - HPMS displays one module for reporting both Part C and Part D Plan Oversight of Agents data.
 - If a contract does not have any licensed agents, it is appropriate to report all zeros for each element.
 - Complaints refer to both complaints from the HPMS Complaint Tracking Module (CTM) and to other complaints made directly to the MAO or Cost contractor. If a complaint is reported to an organization that cannot be tied to a particular contract, the complaint should be reported under all contracts that the agent is licensed to sell.
 - A complaint could result in “disciplinary action” along a broad continuum, from manager-coaching, documented verbal warning, re-training, a documented corrective action plan, suspension, or termination of employment or contract. Any disciplinary action along this continuum would be reportable. A short term revocation (e.g., 1-2 days) is among those which CMS will require reporting. Note that disciplinary action refers to action taken by the Part D sponsor.
 - Reporting is required regardless of the plan’s enrollment status.
 - Refer to Part C Technical Specifications for additional guidance.

XV. Summary of CY2012 Part D Reporting Requirements

| Section | Report Level | Frequency | Report Period(s) | Data Due date(s) |
|---|--|------------|---|--|
| Enrollment and Disenrollment | Contract | Quarterly | 1/1/2012 - 3/31/2012; 4/1/2012 - 6/30/2012; 7/1/2012 - 9/30/2012; 10/1/2012 - 12/31/2012 | 5/31/2012 8/31/2012 11/30/2012 2/28/2013 |
| Retail, Home Infusion, and Long-Term Care Pharmacy Access | Subsection I: Contract; Subsections II and III: PBP | Annually | Subsection I: 1/1/2012 - 3/31/2012; Subsections II and III: 1/1/2012 - 12/31/2012 | Subsection I: 5/31/2012 Subsections II and III: 2/28/2013 |
| Access to Extended Day Supplies at Retail Pharmacies | Contract | Annually | 1/1/2012 - 3/31/2012 | 5/31/2012 |
| Medication Therapy Management Programs | Contract | Annually | 1/1/2012 - 12/31/2012 | 2/28/2013 |
| Prompt Payment by Part D Sponsors | Contract | Biannually | 1/1/2012-6/30/2012; 7/1/2012 - 12/31/2012 | 8/31/2012 2/28/2013 |
| Pharmacy Support of Electronic Prescribing | Contract | Annually | 1/1/2012 - 3/31/2012 | 5/31/2012 |
| Grievances | PBP | Quarterly | 1/1/2012 - 3/31/2012; 4/1/2012 - 6/30/2012; | 5/31/2012 8/31/2012 |

| Section | Report Level | Frequency | Report Period(s) | Data Due date(s) |
|---|--------------|--|--|---|
| | | | 7/1/2012 - 9/30/2012; 10/1/2012 - 12/31/2012 | 11/30/2012 2/28/2013 |
| Pharmacy & Therapeutics (P&T) Committees/ Provision of Part D Functions | Contract | Subsection I: Annually Subsection II: Quarterly | Subsection I: 1/1/2012 - 12/31/2012; Subsection II: 1/1/2012 - 3/31/2012; 4/1/2012 - 6/30/2012; 7/1/2012 - 9/30/2012; 10/1/2012 - 12/31/2012 | Subsection I: 2/28/2013 Subsection II: 5/31/2012 8/31/2012 11/30/2012 2/28/2013 |
| Coverage Determinations and Exceptions | PBP | Quarterly | 1/1/2012 - 3/31/2012; 4/1/2012 - 6/30/2012; 7/1/2012 - 9/30/2012; 10/1/2012 - 12/31/2012 | 5/31/2012 8/31/2012 11/30/2012 2/28/2013 |
| Redeterminations | PBP | Quarterly | 1/1/2012 - 3/31/2012; 4/1/2012 - 6/30/2012; 7/1/2012 - 9/30/2012; 10/1/2012 - 12/31/2012 | 5/31/2012 8/31/2012 11/30/2012 2/28/2013 |
| Long-Term Care (LTC) Utilization | Contract | Biannually | 1/1/2012 - 6/30/2012; | 8/31/2012 |

| Section | Report Level | Frequency | Report Period(s) | Data Due date(s) |
|---|---------------------|------------------|-------------------------|-------------------------|
| | | | 7/1/2012 - 12/31/2012 | 2/28/2013 |
| Fraud, Waste and Abuse Compliance Programs | Contract | Annually | 1/1/2012 - 12/31/2012 | 2/28/2013 |
| Employer/Union-Sponsored Group Health Plan Sponsors | PBP | Annually | 1/1/2012 - 12/31/2012 | 2/28/2013 |
| Plan Oversight of Agents | Contract | Annually | 1/1/2012 - 12/31/2012 | 2/28/2013 |